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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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PERKINS COIE LLP PATENT-SEA P.O. BOX 1247 SEATTLE, WA 98111-1247			EXAMINER REIDEL, JESSICA L	
			ART UNIT 3766	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/731,892

Applicant(s)

SHEFFIELD ET AL.

Examiner

Jessica L. Reidel

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4-7,9-23,25-27,32-43,45-55,61-70 and 72-86 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 74 and 82 is/are allowed.
- 6) ☒ Claim(s) 1,4-7,9-12,14-23,25-27,32-43,45-57,61-70,72,73,75-81 and 83-86 is/are rejected.
- 7) ☒ Claim(s) 13 and 48 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 4/07.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. Acknowledgement is made of Applicant's Amendment, which was received by the Office on February 27, 2007. Claims 2-3, 8, 24, 28-31, 44, 56-60 and 71 have been cancelled. Claims 1, 4-7, 9-23, 25-27, 32-43, 45-55, 61-70 and 72-86 are pending.

### *Priority*

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/432,073, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, there is not support in the disclosure of Application No. 60/432,073 for a method for selecting a stimulation site in a language disorder patient or for treating a language disorder of a patient.

***Information Disclosure Statement***

3. The information disclosure statement (IDS) submitted on April 6, 2007 has been acknowledged and is being considered by the Examiner.

4. Applicant should note that the large number of references in the attached IDS have been considered by the Examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. See MPEP 609.05(b). Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

***Specification***

5. The abstract of the disclosure is objected to because it contains phrases such as "are disclosed" which may be implied. Correction is required. See MPEP § 608.01(b).

6. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. ***Claim 77 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stypulkowski (U.S. 6,944,497) in view of Firlik '419 and Firlik et al. (U.S. 2002/0087201) (herein Firlik '201).*** Stypulkowski discloses a method for treating a language disorder (i.e. stuttering) of a patient comprising selecting a predetermined stimulation site of a patient's brain (see Stypulkowski Abstract and column 3, lines 29-34), the stimulation site being located within the patient's skull, positioning at least one electrode located at the distal portion of a lead 22A at the stimulation site, coupling the at least one electrode to an implantable signal generator, read as a source of electrical potential 16 (see Stypulkowski Fig. 1, column 5, lines 63-65 and column 6, lines 13-24), and at least reducing a language disorder of the patient by applying electrical

stimulation directly to the stimulation site via the at least one electrode (see Stypulkowski column 3, lines 34-41, column 9, lines 61-67 and column 10, lines 1-14). Stypulkowski further discloses that the method includes engaging the patient in a language-based comprehension task while applying the electrical stimulation (see Stypulkowski Fig. 4 and column 7, lines 23-44). Stypulkowski discloses the claimed invention as previously discussed except that it is not specified that the stimulation site be located proximate the dura mater, and outside a cortical surface of the patient's brain.

Both Firlik '419 and Firlik '201, however, teach that it is well known in the art of electrical brain stimulation to choose a stimulation site proximate the dura mater 706 and outside a cortical surface of a patient's brain (see Firlik '201 Figs. 6-40, page 9, paragraphs 99-105 and Firlik '419 Figs. 6-40 and page 10) in order to provide a less invasive means for effecting deep brain stimulation to treat a patient having impaired cognitive function (see Firlik '201 page 2, paragraphs 12-14 and pages 10-21 and Firlik '419 page 2, paragraphs 13-14, page 6, paragraph 73 and pages 7-18). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Stypulkowski in view of Firlik '419 and Firlik '201 to locate the stimulation site proximate the dura mater, and outside a cortical surface of the patient's brain since such a modification would provide a means for effecting deep brain stimulation without inducing serious complications from a highly invasive procedure.

10. *Claims 19-20, 22-23, 25-27, 32, 35-39, 78-79 and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schiff (U.S. 5,938,688) in view of Firlik '419 and Firlik '201.* As to Claims 79 and 86, Schiff expressly discloses a method for treating a patient having impaired cognitive function comprising selecting one or more subdivisions of the patient's

intralaminar nuclei for stimulation, read as selecting a stimulation site of a patient's brain, the stimulation site being located within the patient's skull (see Schiff column 5, lines 63-67, column 6, lines 1-44, column 11, lines 39-44 and column 19, lines 1-18), positioning at least one electrode at the stimulation site (see Schiff column 5, lines 53-63 and column 19, lines 30-31), coupling the at least one electrode, via an insulated conductor, to a voltage control and pulse generator, read as a source of electrical potential (see Schiff column 6, lines 57-60) and restoring at least a portion of the cognitive function and eliminating the disorder of interest by applying electrical stimulation directly to the stimulation site via the at least one electrode (see Schiff Abstract, column 2, lines 16-23, column 4, lines 58-62 and column 18, lines 1-13). Schiff discloses the claimed invention as previously discussed except that it is not specified that the stimulation site be located proximate the dura mater, and outside a cortical surface of the patient's brain.

Both Firlik '419 and Firlik '201, however, teach that it is well known in the art of electrical brain stimulation to choose a stimulation site proximate the dura mater 706 and outside a cortical surface of a patient's brain (see Firlik '201 Figs. 6-40, page 9, paragraphs 99-105 and Firlik '419 Figs. 6-40 and page 10) in order to provide a less invasive means for effecting deep brain stimulation to treat a patient having impaired cognitive function (see Firlik '201 page 2, paragraphs 12-14 and pages 10-21 and Firlik '419 page 2, paragraphs 13-14, page 6, paragraph 73 and pages 7-18). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Schiff in view of Firlik '419 and Firlik '201 to locate the stimulation site proximate the dura mater, and outside a cortical surface of the

patient's brain since such a modification would provide a means for effecting deep brain stimulation without inducing serious complications from a highly invasive procedure.

11. As to Claims 19, 35-37 and 78, Schiff expressly discloses a method for treating a patient having impaired cognitive function comprising selecting one or more subdivisions of the patient's intralaminar nuclei for stimulation, read as selecting a stimulation site of a patient's brain, the stimulation site being located within the patient's skull (see Schiff column 5, lines 63-67, column 6, lines 1-44, column 11, lines 39-44 and column 19, lines 1-18), positioning at least one electrode at the stimulation site (see Schiff column 5, lines 53-63 and column 19, lines 30-31), coupling the at least one electrode, via an insulated conductor, to a voltage control and pulse generator, read as a source of electrical potential (see Schiff column 6, lines 57-60) and restoring at least a portion of the cognitive function and eliminating the disorder of interest by applying electrical stimulation directly to the stimulation site via the at least one electrode (see Schiff Abstract, column 2, lines 16-23, column 4, lines 58-62 and column 18, lines 1-13). Schiff discloses at column 6, lines 45-46 that the "electrical stimulation can be continuous, intermittent or periodic". The Examiner takes the position that it is inherent or at least obvious to one having ordinary skill in the art that if the stimulation is applied continuously, then at least a portion of that stimulation is applied while not actively engaging the patient in a language-based task.

The method of Schiff is disclosed as a general practice for treating patient's who's cognitive dysfunction is, for example, produced, at least in part, by brain injuries including stroke, head trauma, toxicological agents, anoxia, ischemia, nutritional deficiencies, developmental diseases, infections diseases, neoplastic diseases, degenerative diseases, complications thereof, or other structural lesions (see Schiff column 2, lines 61-67 and column 3,



lines 1-4). It is inherent that a cognitive dysfunction typically produced by stroke is a language-based disorder. Schiff also discloses that the impaired cognitive function capable of being treated by the disclosed method can include impaired semantic information processing (i.e. impaired language processing) and that aphasia screening tests may be used to diagnose a patient having impaired semantic information processing due to stroke. It is inherent that a patient experiencing impaired semantic information processing or even a patient that displays aphasia would suffer from a language-based disorder, thus the method treats such impaired cognitive function (see Schiff column 2, lines 24-26 and column 3, lines 60-64). Schiff discloses the claimed invention as previously discussed except that it is not specified that the stimulation site be located proximate the dura mater, and outside a cortical surface of the patient's brain.

Both Firlik '419 and Firlik '201, however, teach that it is well known in the art of electrical brain stimulation to choose a stimulation site proximate the dura mater 706 and outside a cortical surface of a patient's brain (see Firlik '201 Figs. 6-40, page 9, paragraphs 99-105 and Firlik '419 Figs. 6-40 and page 10) in order to provide a less invasive means for effecting deep brain stimulation to treat a patient having impaired cognitive function (see Firlik '201 page 2, paragraphs 12-14 and pages 10-21 and Firlik '419 page 2, paragraphs 13-14, page 6, paragraph 73 and pages 7-18). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Schiff in view of Firlik '419 and Firlik '201 to locate the stimulation site proximate the dura mater, and outside a cortical surface of the patient's brain since such a modification would provide a means for effecting deep brain stimulation without inducing serious complications from a highly invasive procedure.

12. As to Claim 20, Firlik '201 and Firlik '419 both expressly disclose that electrodes 660 are implanted at the stimulation site that is proximate a dura mater 706 and outside a cortical surface of a patient's brain to provide a means for effecting deep brain stimulation without inducing serious complications (i.e. minimally invasive) (see Firlik '201 and Firlik '419, entire documents).

13. As to Claims 22-23, the previously modified Schiff reference discloses the claimed invention as previously discussed but does not expressly disclose that the electrical stimulation include applying the electrical stimulation to either the right or left hemisphere of the brain. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the method as taught by Schiff in view of Firlik '201 and Firlik '419 to apply the electrical stimulation to either the left or right hemisphere of the brain, because Applicant has not disclosed that applying stimulation at either location provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the stimulation applied proximate the dura mater and outside a cortical surface of a patient's brain as taught by Schiff in view of Firlik '201 and Firlik '419, because it provides a means for effecting deep brain stimulation without inducing serious complications (i.e. minimally invasive) and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Schiff in view of Firlik '201 and Firlik '419.

Therefore, it would have been an obvious matter of design choice to modify Schiff in view of Firlik '201 and Firlik '419 to obtain the invention as specified in the claims.

14. Regarding Claim 25, as discussed above, aphasia screening tests may be used to diagnose a patient having impaired semantic information processing due to stroke and that the method disclosed may be used as a general practice for treating patient's who's cognitive dysfunction is a result of stroke. It is inherent, or at least obvious to one having ordinary skill in the art at the time of the invention, that the stimulation method for improving such cognitive function applied to a patient identified via aphasia screening tests would experience reduction in aphasia upon stimulation (see Schiff column 2, lines 24-26 and 61-67 and column 3, lines 1-4 and 60-64).

15. As to Claim 26, the Examiner takes the position that the applying the electrical stimulation to any area of the brain is synonymous with applying electrical stimulation "at least proximate" to at least one of Broca's area, Wernicke's area and neuronal connections extending between Broca's area and Wernicke's area, with "at least proximate" meaning "relatively near".

16. As to Claim 27, the previously modified Schiff reference discloses the claimed invention as previously discussed but does not expressly disclose that the electrical stimulation include applying the electrical stimulation to at least one of the middle temporal gyrus, the retrosplenial cortex and the retrosplenial cuneus of the brain. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the method as taught by Schiff in view of Firlik '201 and Firlik '419 to apply the electrical stimulation to either the middle temporal gyrus, the retrosplenial cortex or the retrosplenial cuneus of the brain, because Applicant has not disclosed that applying stimulation to any of these locations provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the stimulation applied proximate the dura mater and outside a cortical surface of a patient's brain as taught by Schiff in

view of Firlik '201 and Firlik '419, because it provides a means for effecting deep brain stimulation without inducing serious complications (i.e. minimally invasive) and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Schiff in view of Firlik '201 and Firlik '419.

Therefore, it would have been an obvious matter of design choice to modify Schiff in view of Firlik '201 and Firlik '419 to obtain the invention as specified in the claims.

17. As to Claim 32, Schiff discloses that the method may further comprise administering a neuroexcitatory drug to the patient in conjunction with the electrical stimulation, read as applying the electrical stimulation while the neuroexcitatory drug is active in the patient's body (see Schiff column 5, lines 34-52).

18. As to Claims 33-34, Schiff discloses that range of stimulation frequencies and intensity of stimulation will depend on, impedance of the electrode once in the brain, excitation properties of cells which may differ within subdivisions of the intralaminar nuclei, *the type of induced physiologic responses sought for a particular patient*, and inter-individual variation [emphasis added] (see Schiff column 6, lines 45-51). Schiff discloses the claimed invention as discussed above except that it is not specified that the stimulation be applied below, at or about a level that causes movement, speech or sensation in the patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to stimulate the patient with stimulation below, at or about a level that causes movement, speech or sensation in the patient, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering an optimum value of a result effective variable involves only routine skill in the art.

19. As to Claim 38, Schiff disclose that applying an electrical stimulation includes applying a varying electrical stimulation signal having a frequency of from about 1Hz to 1kHz (see Schiff column 6, lines 53-54).

20. As to Claim 39, Schiff discloses that applying an electrical stimulation includes applying a varying electrical stimulation signal having an electrical potential of from about 0.1 volts to about 10 volts (see Schiff column 7, lines 1-3).

21. *Claims 1-7, 9-12, 14-18, 21, 40-43, 45-47, 49-55, 61-70, 72-73, 75-76, 80-81 and 83-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schiff in view of Firlik '419 and Firlik '201 and in further view of McDermott (U.S. 2004/0082847) and Binder.* As to Claims 1, 6-7, 9-11, 17-18, 21, 40-43, 45-46, 55, 61-64, 66-70, 72-73, 75-76, 80-81 and 83-85, the previously modified Schiff reference discloses the claimed invention as discussed above except that the method does not further comprise directing the patient to perform a language based task including directing the patient to perform a task that requires no verbal output, directing information to be collected corresponding to a level of neural activity in the patient's brain while the patient performs the language based task and selecting the stimulation site based at least in part on the information.

McDermott, however, discloses a method of identifying one or more language regions in the brain of a subject. The method includes directing the patient to perform a language based task including directing the patient to perform a task that requires no verbal output, directing information to be collected corresponding to a level of neural activity in the patient's brain while the patient performs the language based task and locating and/or identifying one or more language regions in the brain based at least in part on the information (see McDermott Abstract

and page 2, paragraphs 16-25) and Brinder. McDermott also discloses that although the method is typically used in conjunction with surgery, the invention may be practiced in a variety of surgical and non-surgical environments in which it may be desirable to locate brain regions that support language (see McDermott page 1, paragraphs 6 and 15). In addition Schiff discloses that it is preferable to identify the subdivision of the brain that modulates the specific cognitive function that is impaired in the patient to be treated with electrical stimulation for electrode placement via microelectrode and micro stimulation mapping techniques (see Schiff column 5, lines 63-67, column 6, lines 1-44 and column 11, lines 39-44). McDermott discloses that it is desirable to use such functional MRI techniques for pre-operative language area mapping so that surgical electrical stimulation mapping might be avoided. McDermott further discloses that the methods disclosed utilizing such functional MRI techniques to identify the language areas of the brain are more precise than invasive techniques known in the art (see McDermott page 1, paragraph 6). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Schiff in view of McDermott to include directing the patient to perform a language based task including directing the patient to perform a task that requires no verbal output, directing information to be collected corresponding to a level of neural activity in the patient's brain while the patient performs the language based task and selecting the stimulation site based at least in part on the information in order to precisely identify the subdivision of the brain that modulates the specific cognitive function (such as language) that is impaired in the patient to be treated with the electrical stimulation.

Applicant differs from the modified Schiff reference in that the method also includes directing the patient to repeat a noun, directing the patient to silently generate a verb associated

with a common noun, directing a patient to retrieve a word based on a letter cue (audio or visual) and directing the patient to respond nonverbally to an oral task that requires the patient to understand the difference between two auditory commands. The Examiner considers the use of these different semantic decisions and language based tasks within functional MRI screening as a means to accurately locate the language centers in the brain to be conventional and well known in the art with Binder being but on example. Binder discusses methods of directing a patient to silently generate a verb associated with a common noun, directing a patient to retrieve a word based on a letter cue (audio or visual) and directing the patient to respond nonverbally to an oral task that requires the patient to understand the difference between two auditory commands within fMRI to accurately locate the language centers in the brain by comparing the images acquired during the different tasks to each other (see Binder page 384, columns 1-2, page 385, columns 1-2, page 386, columns 1-2 and page 387, column 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the fMRI tasks given in the method of Schiff in view of McDermott to further include the additional steps of directing a patient to silently generate a verb associated with a common noun, directing a patient to retrieve a word based on a letter cue (audio or visual) and directing the patient to respond nonverbally to an oral task that requires the patient to understand the difference between two auditory commands within fMRI to accurately locate the language centers in the brain by comparing the images acquired during the different tasks to each other in order to better the invention.

22. As to Claims 4-5 the Examiner takes the position that the selecting a stimulation site on or in any area of the brain is synonymous with selecting a stimulation site "at least proximate" to

at least one of Broca's area, Wernicke's area, neuronal connections extending between Broca's area and Wernicke's area the middle temporal gyrus, the retrosplenial cortex and the retrosplenial cuneus of the brain, with "at least proximate" meaning "relatively near".

23. As to Claims 14 and 49, McDermott discloses that directing information to be collected includes directing a computer-based routine to collect and process the information (see McDermott page 3, paragraph 32 and page 4, paragraph 39).

24. As to Claims 15 and 50, McDermott further discloses that the method includes directing the formation of an image of at least a portion of the patient's brain, with at least a portion of the image having features representative of the information (see McDermott Figs. 2-5 and page 4, paragraphs 40-46).

25. As to Claims 16 and 51, McDermott discloses that two types of language function may be shown on an fMRI brain scan. With reference to McDermott Fig. 2, row 30 depicts differences in activity for the two list types at row 130 and row 230. The image includes a first region with a characteristic of the first region having a first value (regions preferentially active for the phonological task) and a second region with a characteristic of the second region having a second value different than the first value (regions preferentially active for the semantic task) (see McDermott Fig. 2 and page 4, paragraph 46).

26. As to Claim 47, Schiff discloses that the method may further comprise administering a neuroexcitatory drug to the patient in conjunction with the electrical stimulation, read as applying the electrical stimulation while the neuroexcitatory drug is active in the patient's body (see Schiff column 5, lines 34-52).



Art Unit: 3766

27. As to Claim 52, McDermott discloses that functional images are collected with an asymmetric spin-echo planar sequence sensitive to blood-oxygen-level-dependant (BOLD) contrast (see McDermott page 2, paragraph 23).

28. As to Claims 12, 53-54 and 65, Firlik '201 and Firlik '419 both expressly discloses that electrodes 660 are implanted at the stimulation site that is proximate a dura mater 706 and outside a cortical surface of a patient's brain to provide a means for effecting deep brain stimulation without inducing serious complications (i.e. minimally invasive) (see Firlik '201 and Firlik '419, entire documents).

#### *Response to Arguments*

29. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

#### *Allowable Subject Matter*

30. Claims 13 and 48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

31. Claims 74 and 82 are allowed.

#### *Conclusion*

32. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

33. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

34. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3766

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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